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**AUG 10 2004**

Patent Application Serial No.: 10/020,882

Our Ref: PT-1949001

**CUSTOMER NO. 23607**

Applicants: Dialysis Solutions Inc.

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**OFFICIAL**

Title: STERILE LOW BICARBONATE DIALYSIS CONCENTRATE

Inventor: Sheldon Tobe

Examiner: Leslie R. Deak

Group Art Unit: 3762

Due Date: August 13, 2004

No. of Pages including this sheet: 8

**DELIVERED TO FACSIMILE NO. (703) 872-9306**

August 10, 2004

Commissioner of Patents  
U.S. Patent and Trademark Office  
220 20<sup>th</sup> Street S.  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Attention: Leslie R. Deak

Dear Ms. Deak:

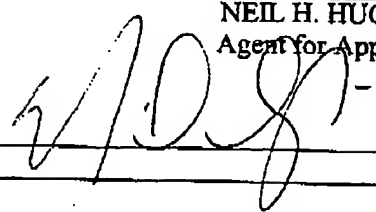
**CERTIFICATION OF FACSIMILE TRANSMISSION**

I hereby certify that this paper:

1) Response to Examiner's Report dated July 13, 2004

is being facsimile transmitted to the United States Patent Office Facsimile  
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NEIL H. HUGHES  
Agent for Applicant

Signature: 

Date: August 10, 2004



## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,882	12/19/2001	Sheldon Tobe	PT-1949001	8815

23607 7590 07/13/2004

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 175 COMMERCE VALLEY DRIVE WEST  
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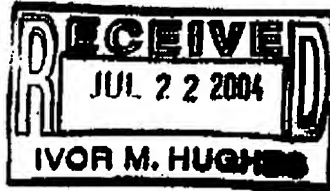
EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3702

DATE MAILED: 07/13/2004



Due: Aug. 13/04

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/020,882

Applicant(s)

TOBE, SHELDON

Examiner

Leslie R. Deak

Art Unit

3762

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 9, 10, 14, and 17, drawn to a sterile dialysis concentrate composition, classified in class 424, subclass 686.
  - II. Claims 2 and 3, drawn to a kit comprising the concentrate solution and instructions, classified in class 514, subclass 512.
  - III. Claims 4, 6, 11, and 12, drawn to a method for preparing a dialysis concentrate solution, classified in class 424, subclass 489.
  - IV. Claims 5, 7, 8, 13, 15, and 16 drawn to a method of performing patient treatment, classified in class 604, subclass 5.01.

The inventions are distinct, each from the other because of the following reasons:

1. The inventions in all four groups are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d).
2. Applicant's election with traverse of the restriction in the reply filed on 15 April 2004 is acknowledged. The traversal is on the ground(s) that each invention is not distinct since they all require use of the claimed composition. This is not found persuasive.
3. Applicant has argued that the invention requires the claimed composition in the claimed kit. However, the claimed composition may be used in a different kit, therefore making the inventions independent and distinct. Furthermore, the composition may be used in another procedure, prepared in another manner, and can be used in a different procedure. While each of

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the dependent claims talks about the composition, the claimed composition may be used in a variety of applications, and claims drawn to its use and preparation are statement of intended use of the claimed composition. The claims are clearly divisible into four distinct categories of invention, regardless of their dependency: the composition of a sterile dialysis solution; a kit for use with the composition; a method for preparing a composition; and a method of performing hemodialysis.

4. The requirement is still deemed proper. However, since the rationale has changed, the requirement is not final at this time.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. The preambles to the claims indicate that the claim limitations are drawn to separate and distinct subject matter. In order to more particularly claim the intended subject matter, the claims that directed to the distinct groups: concentrate, kit, method of mixing, and method of patient treatment, should be rewritten in independent form with corresponding dependent claims.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

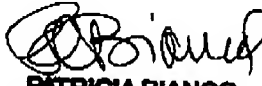
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd  
8 July 2004

  
PATRICIA BIANCO  
PRIMARY EXAMINER  
7/9/04